product receives marketing exclusivity, FDA will not approve (or, in limited cases, even receive) an ANDA for the drug product during that time period.

Respondents to this collection of information are new drug and abbreviated new drug applicants.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
314.50(i)	8	1	8	2	16
314.50(j)	50	1	50	2	100
314.52	8	1	8	8	64
314.53	200	1	200	1	200
314.54(a)(1)(vii)	8	1	8	1	8
314.70(f)	43	1	43	1	43
314.94(a)(12)	395	1	395	2	790
314.95	30	1	30	16	480
314.107(c)(4), (e)(2)(iv), (f)(2), (f)(3)	30	1	30	1	30
Total					1,731

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

This estimate is based on FDA's experience over the last 3 years in receiving this information, and the familiarity by FDA reviewers with the amount of time it takes to prepare and submit the information to FDA.

Dated: December 5, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–32553 Filed 12–11–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0320]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Filing Objections and Requests for a Hearing on a Regulation or Order'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 6, 1997 (62 FR 42257 to 42258), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0184. The approval expires on September 30, 2000.

Dated: December 5, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–32583 Filed 12–11–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0443]

Iron-Containing Supplements and Drugs: Label Warning Statements and Unit-Dose Packaging Requirements; Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a small entity compliance guide entitled ''Iron-Containing Supplements and Drugs: Label Warning Statements and Unit-Dose Packaging Requirements; Small Entity Compliance Guide'' (compliance guide). This compliance guide is intended to help small entities comply with the final rule requiring label warnings and unit-dose packaging for iron-containing supplements and drug products. This action is being taken under the Small Business Regulatory Enforcement Fairness Act of 1996 (the SBREFA).

DATES: Written comments on the compliance guide may be submitted at any time.

ADDRESSES: An electronic version of the compliance guide entitled ''Iron-Containing Supplements and Drugs: Label Warning Statements and Unit-Dose Packaging Requirements; Small Entity Compliance Guide'' is available on the Internet at ''http://vm.cfsan.fda.gov/~dms/secqiron.html''. Printed copies may be obtained from the Iron Labeling and Packaging, Industry Activities Staff (HFS–565), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204. Submit written comments on the compliance guide to the contact person below.

FOR FURTHER INFORMATION CONTACT: Linda S. Kahl, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3101.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 15, 1997 (62 FR 2218), FDA issued a final rule requiring: (1) Label warning statements on products taken in solid oral dosage form to supplement the dietary intake of iron or to provide iron for therapeutic purposes and (2) unit-dose packaging for iron-containing products that contain 30 milligrams or more of iron per dosage unit. This final rule became effective July 15, 1997.